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Economic assessment of implementing Hexaxim® vaccine within the South African Expanded Programme on Immunisation (EPI-SA)

M. Mogale [1], R.J. Burnett [1], D. Olivier [2], J. Mphahlele [1,*]

[1] *University of Limpopo (Medunsa Campus), Medunsa, Pretoria, South Africa*
[2] *Quark Healthcare Consulting (Pty) Ltd, Pretoria, South Africa*

Background: The South African Expanded Programme on Immunisation (EPI-SA) currently vaccinates against 10 childhood vaccine preventable diseases. Six injections are required for primary vaccination against diphtheria, tetanus, pertussis, polio, *Haemophilus influenza* type b and hepatitis B: three DTaP-IPV//Hib [Pentaxim®] doses and three monovalent Hep B vaccines to children under 12 months of age, with a seventh injection (Pentaxim® booster) at 18 months. Madhi et al (PIDJ 30:e68 2011) demonstrated no significant difference in the safety and efficacy between Pentaxim® plus monovalent Hep B and a new fully liquid hexavalent vaccine, Hexaxim® (DTaP-IPV-Hib-HepB). From a healthcare provider perspective, combination vaccines could reduce costs, simplify logistics and delivery infrastructure, and improve coverage with fewer injections. This study aimed to analyse the cost implications of a switch from the current combination of Pentaxim® plus monovalent Hep B injections, to a single Hexaxim® injection, from the public sector perspective.

Methods & Materials: Data were collected to derive direct costs, i.e. vaccines' prices (except Hexaxim®, no price yet available), transportation charges, cold chain storage, vaccine wastage rate, hazardous waste disposal and vaccine administration. All costs were calculated per dose, and expressed in South African Rand (R) (USD 1.00 = R10.19 per 2013 exchange rate). Indirect costs such as individual and societal benefits were excluded.

Results: Delivering one dose ofPentaxim® and Hep B costs R166.30. Reduced volumes result in cost reductions when using Hexaxim® for: cold storage; hazardous waste disposal; and vaccine administration, resulting in an estimated saving of R10.52 to R29.40 per dose, depending on utilisation of usable cold storage space.

Conclusion: Implementation of Hexaxim® within EPI-SA is highly recommended, because it reduces healthcare provider costs by simplifying logistics and delivery infrastructure. From a community perspective, such vaccines reduce clinic visits, vaccinators' errors, number of injections and side effects, which translate to better acceptability, convenience and increased compliance. As the use of Hexaxim® demonstrates direct and indirect cost savings, potential public sector introduction should be valued not only in terms of the price of Pentaxim® and Hep B.

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Efficacy and immunogenicity of inactivated influenza vaccine in pregnant women: A randomized, double-blind, placebo controlled trial

S. Madhi [1,*], C. Cutland [2], A. Hugo [2], S. Jones [2], L. Kuwanda [2], B. Dighero [3], F.K. Treurnicht [1], K. Klugman [4], M. Venter [1], E.A.F. Simoes [5], K. Neuzil [6], J. Ortiz [6], A. Weinberg [3], M.S.C. Nunes [2]

[1] *National Institute for Communicable Diseases (NICD), Johannesburg, South Africa*
[2] *University of the Witwatersrand, Johannesburg, South Africa*
[3] *University of Colorado, Anschutz Medical Campus, Aurora, USA*
[4] *Emory University, Atlanta, GA, USA*
[5] *University of Colorado Denver, Denver, USA*
[6] *PATH, Seattle, USA*

Background: Pregnant women are at increased susceptibility to severe influenza-illness and are recommended by WHO to be a priority group for influenza vaccination. The aims of our study were to assess the immunogenicity of trivalent IIV (IIV3) in pregnant women vaccinated during their 2nd/3rd trimester and to calculate the vaccine efficacy (VE) to PCR-confirmed influenza illness (PCI).

Methods & Materials: A double-blind, randomized, placebo-controlled trial was undertaken in Soweto, South Africa in 2011 and 2012. 2116 confirmed HIV-uninfected pregnant women were randomized to receive either IIV3 or normal saline placebo intramuscularly. Immune responses to each vaccine-strain, using hemagglutination-inhibition (HAI) assays were measured pre-vaccination and one month post-vaccination. HAI titres of $\geq$1:40 were categorized as seroprotective and seroconversion was defined as at least a 4-fold increase in titres from pre- to post-vaccination. Participants were followed until six months post-partum for the presence of acute respiratory illness or hospitalization for acute cardio-pulmonary illness. When ILI was confirmed by a study physician oropharyngeal and nasopharyngeal swabs were collected for influenza virus testing by real-time PCR.

Results: One month post-vaccination, comparing IIV3 and placebo-recipients, the proportion of women who seroconverted were 72.5% vs. 8.1% to A/H1N1pdm09, 64.8% vs. 2.7% to H3N2, 92.3% vs. 2.0% to influenza-B strain (all comparisons $p < 0.001$). Post-vaccination, the proportion of women with seroprotective HAI titres were 93.7% vs. 48.0% for A/H1N1pdm09, 78.9% vs. 27.0% for H3N2 and 97.2% vs. 29.1% for influenza-B ($p < 0.001$ for all comparisons). The vaccine efficacy of IIV3 was 46.1% (95%CI: 6.4% to 69.0%) in protecting against PCI due to homotypic vaccine strains and 50.4% (95%CI: 14.5 to 71.2) when including the 3 non-vaccine influenza B-Yamagata cases that exclusively occurred among the placebo-recipients. The dominant strain of influenza virus identified was H3N2 which composed 22 (57.9%) cases in the placebo group and 10 (52.6%) in the vaccinees. 174 and 181 IIV-recipients and placebo-recipients, respectively, had at least one ILI medical visit. IIV3 was not associated with reduction of first episode of ILI (VE: 4.6%; 95%CI: -15.4% to 21.1%).